MAY 1 5 2013

10. 510(K) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

The Assigned 510(k) number is k130463

Submitter: UCP Biosciences, Inc
1445 Koll Circle, Ste 111
San Jose, CA 95014
Tel: 408-392-0064
Fax: 408-392-0163

Date: May 13, 2013

Contact Person: Dr. Nancy Chen

Trade Name: UCP Home™ Drug Screening Test Cards,
UCP Home™ Drug Screening Test Cups

Common Name:
Amphetamine Test System
Methamphetamine Test System
Cocaine Test System
Barbiturate Test System
Benzodiazepine Test System
Buprenorphine Test System
Methamphetamine Test System (MDMA)
Opiates Test System
Methadone Test System
Opiates Test System (Oxycodone)
Amphetamine Test System (Enzyme Immunoassay Phencyclidine)
Cannabinoid Test System
Propoxyphene Test System
Tricyclic Antidepressant Test System

Product Code: DKZ, DIO, DIS, JXM, DJC, DJR, DJG, LCM, LDJ, LFG, JXN

Regulation Section:

CFR 21 § 862.3100
CFR 21 § 862.3150
CFR 21 § 862.3170
CFR 21 § 862.3250
CFR 21 § 862.3610
CFR 21 § 862.3620
CFR 21 § 862.3650

CFR 21 § 862.3870
CFR 21 § 862.3910
CFR 21 § 862.3700
Unclassified, Enzyme immunoassay, Phencyclidine

Panel: Toxicology (91)

Device Classification: II

Substantially Equivalent Devices:

UCP Home™ Drug Screening Test Cards/UCP Home™ Drug Screening Test Cups (k091588), UCP Drug Screening Test Cups (k110515)

Product Description:

UCP Home Drug Screening Tests are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Amphetamine, Barbiturates, Benzodiapines, Buprenorphine, Cocaines, Marijuana, Methamphetamine, MDMA, Methadone, Opiates, Opiates 300, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants and their metabolites at the cut-off levels as indicated. The tests can be performed without the use of an instrument.

Intended Use:

UCP Home™ Drug Screening Test Cards, UCP Home™ Drug Screening Test Cups:

The UCP Home Drug Screening Test Cups, UCP Home Drug Screening Test Cups are rapid, qualitative, competitive binding immunoassays for the detection of the following drugs and their metabolites in human urine:

Test	Calibrator	Cut-off
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 ng/mL
Buprenorphine	Buprenorphine	10 ng/mL
Cocaine	Benzoylecgonine	300 ng/mL
Marijuana	Delta-9-THC-COOH	50 ng/mL
Methadone	Methadone	300 ng/mL
Methamphetamine	D-Methamphetamine	1000 ng/mL
MDMA	MDMA	500 ng/mL
Morphine	Morphine	300 ng/mL
Opiates 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL

Propoxyphene	Propoxyphene	300 ng/mL
Tricyclic Antidepressant	Nortriptyline	1000 ng/mL

The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. The tests are intended for over-the-counter (OTC) use as the first step in a two step process to provide the consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing – the second step in the process, along with the materials for shipping the urine specimen to the laboratory, is provided. The test is also intended for prescription use. The test also is intended for prescription use.

The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene Tricyclic Antidepressant in urine. The tests provide only preliminary data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS).

Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring the drug levels.

For Over-The-Counter (OTC) use and prescription use
For In Vitro Diagnostics only

Comparison to Predicate Devices:

When compared to the predicate (K091588), UCP Home Drug Screening Tests can qualitatively detect Amphetamine, Barbiturates, Benzodiazepine, Cocaine, Marijuana, Methadone, Methamphetamine, MDMA, Morphine, Opiates 2000, Oxycodone, Phencyclidine, Tricyclic Antidepressant and their metabolites in human urine. Both devices utilize the same cutoff concentrations. Both devices are immunochromatographic, lateral flow assays for the qualitative detection of drugs with visual, qualitative end results. Both tests are intended to provide preliminary analytical test results. Both devices are intended for health care professionals use and for OTC consumers use. The UCP Home Drug Screening Tests can detect up to 14 drugs (by also detecting buprenorphine and propoxyphene), whereas the predicates can detect up to 12 drugs.

Safety and Effectiveness Data:

Performance Studies:

The method comparison, precision, specificity (interference and cross-reactivity), cut-off study of each drug test in UCP Home Drug Screening Tests can be found in k091612, k091588, and k061457.

Consumer Studies

The study design and protocol in the consumer study of UCP Home Drug Screening Tests is the same as that described in k091588, k110515, was conducted among 115 lay persons in three geographic regions. Fifty seven females and fifty eight males from ages between 18 and 77 years have participated the study. Fifty seven participants had high school education or less, fifty eight participants had finished college courses. None of the participants had experiences using drug testing products before. The urine samples were prepared to contain strong negative (0% of cutoff), a very weak negative (50% of cutoff), a weak negative (75% of cutoff), a very weak positive (125% of cutoff), a weak positive (150% of cutoff) and high positive (300% of Cutoff). The urine samples with various drug concentrations were prepared by spiking pure drugs or drug metabolites into drug free human urine, the final drug concentrations in each urine sample were confirmed by GC/MS but TCA, TCA concentrations in the urine samples was confirmed by HPLC. The test results performed by the lay users showed 97% or above agreement rate with GC/MS results and indicate the lay users can perform UCP Home Drug Screening Tests satisfactorily by following the test instruction. The post-study survey was conducted to determine if the lay users can understand the test instruction, the meaning of the test results and how to interpret the test results. Consumers were asked 9 questions including whether the test was easy to run, the results was easy to read, how to interpret the test results, importance of confirmatory test and some medicines and foods may affect the test results. Participant responses support that the lay users can understand how to run the test, interpret the test results, the importance of confirmatory test, and some issues concerning certain prescription medicines and foods may affect the test results.

Other Information about Performance Characteristics:

The performance characteristics of UCP Home Drug Screening Tests including the precision study, sensitivity study, specificity and cross reactivity study, interference study and stability study have been also established. The results have demonstrated that UCP Home Drug Screening Tests performs satisfactorily when used according to the package inserts.

Conclusion:

The performance data in this submission supports UCP Home™ Drug Screening Test Cards and UCP Home™ Drug Screening Test Cups are substantially equivalent to the predicate device UCP Home™ Drug Screening Test Cards/ UCP Home™ Drug Screening Test Cups (k091588).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2013

UCP Biosciences, Inc.
C/O Ms. Nancy Chen
1445 Koll Circle, Ste. 111
SAN JOSE CA 95112

Re: K130463
Trade/Device Name: UCP Home Drug Screening Test Cards
UCP Home Drug Screening Test Cups
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DIO, DIS, JXM, DJC, DJR, DJG, LCM, LDJ, LFG, JXN
Dated: March 13, 2013
Received: March 15, 2013

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130463

Device Name: UCP Home Drug Screening Test Cards
UCP Home Drug Screening Test Cups

Indications for Use:

The UCP Home Drug Screening Test Cards, UCP Home Drug Screening Test Cups are rapid, qualitative, competitive binding immunoassays for the detection of the following drugs and their metabolites in human urine:

Test	Calibrator	Cut-off
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 ng/mL
Buprenorphine	Buprenorphine	10 ng/mL
Cocaine	Benzoylecgonine	300 ng/mL
Marijuana	Delta-9-THC-COOH	50 ng/mL
Methadone	Methadone	300 ng/mL
Methamphetamine	D-Methamphetamine	1000 ng/mL
MDMA	MDMA	500 ng/mL
Morphine	Morphine	300 ng/mL
Opiates 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Propoxyphene	Propoxyphene	300 ng/mL
Tricyclic Antidepressant	Nortiptyline	1000 ng/mL

The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. The tests are intended for over-the-counter (OTC) users as the first step in a two step process to provide consumers, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample.

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles-S
2013.05.14 12:31:41 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130463

Information regarding confirmatory testing – the second step in the process, along with the materials for shipping the urine specimen to the laboratory, is provided. The test is also intended for prescription use.

The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressant in urine. The tests provide only preliminary data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS).

Clinical considerations and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring drug levels.

Prescription Use ___x___ And/Or Over the Counter Use ___x___.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles -S
2013.05.14 12:32:35 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130463